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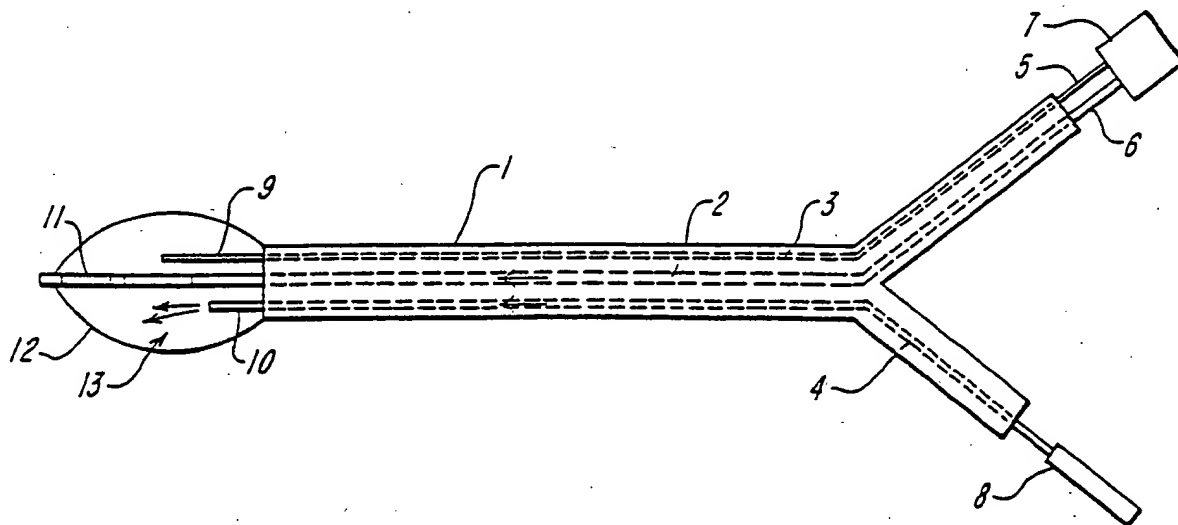
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<p>(21) International Application Number: PCT/US89/02154 (22) International Filing Date: 18 May 1989 (18.05.89) (30) Priority data: 195,584 18 May 1988 (18.05.88) US (71) Applicant: KASEVICH ASSOCIATES, INC. [US/US]; 175V New Boston Street, Woburn, MA 01888 (US). (72) Inventors: KASEVICH, Raymond, S. ; 680 Wellesley Street, Weston, MA 02193 (US). McQUEENEY, James, F. ; 22 Birch Road, Natick, MA 01760 (US). CROOKER, Ronald, H. ; 116 Franklin Street, Stoneham, MA 02180 (US). (74) Agent: WALPERT, Gary, A.; Hale and Dorr, 60 State Street, Boston, MA 02109 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i></p>

(54) Title: MICROWAVE BALLOON ANGIOPLASTY



(57) Abstract

A microwave catheter system used for heating arterial plaque and including a catheter member (1) adapted for positioning in the artery and an inflatable balloon (12) supported at the distal end of the catheter member (1). Microwave energy is coupled by means of a transmission line (2) to an antenna (11). An optic fiber (3) extends through the catheter member and may be used for temperature sensing or other purposes. A channel (4) is provided through the catheter member for coupling a fluid to the bal-

-1-

MICROWAVE BALLOON ANGIOPLASTY

RELATED APPLICATIONS

The present application is a continuation-in-part of application Serial No. 100,465, filed on September 24, 1987, which in turn is a divisional application of U.S. Serial No. 834,199, filed February 27, 1986, and now granted as U.S. Patent No. 4,700,716.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates in general to microwave balloon angioplasty, and pertains more particularly to a microwave or radio frequency catheter system for the heating of plaque in arteries or blood vessels. Also described herein are improvements pertaining to features of the microwave catheter system, including improved antenna constructions and associated fiber optics.

II. Background Discussion

Balloon angioplasty is now a relatively well-accepted alternative to bypass surgery for high-grade obstructive atherosclerotic lesions of the peripheral, renal and coronary vessels. In this regard, U.S. Patent No. 4,643,186, entitled "Percutaneous Transluminal Microwave Catheter Angioplasty," by Rosen et al., describes a coaxial cable and antenna for microwave heating of artery plaque. This system suffers from several shortcomings which make it difficult, if not impossible, to develop a well controlled volume of heat within the plaque material. Also, for small arteries where catheter diameter and flexibility are critical, the system described by Rosen et al. does not allow for sufficient transmission of microwave power to the plaque for

-3-

catheter member adapted for positioning in the artery, and adapted to support at the distal end thereof an inflatable balloon. A microwave signal generator is disposed at the proximal end of the catheter member.

5 A transmission line means couples from the signal generator through the catheter member and includes at its distal end an antenna means. Optic fiber means extends through the catheter member between proximal and distal ends thereof, and has one end thereof
10 disposed in the balloon in juxtaposition with the antenna means. Channel means extend through the catheter member between proximal and distal ends thereof for coupling a fluid to the balloon for inflation thereof.

15 In accordance with further features of the present invention, the channel means has an entrance port to the balloon and further includes a pressurized fluid source for introducing fluid to the balloon under pressure. The signal generator is excited for a
20 predetermined period of time upon injection of the inflating fluid. The optic fiber means has a sensor at the distal end within the balloon to measure temperature in or at the surface of the balloon, and in one embodiment, a pair of sensors are employed for
25 measuring temperature at separate locations within the balloon. The antenna means may comprise a collinear array antenna. This antenna may be disposed inside of the balloon, or may be disposed within the skin forming the balloon. The collinear array antenna may
30 be formed in a spiral to provide full balloon circumferential coverage, or may, alternatively, be formed in a helix.. In still a further embodiment of the invention, the collinear array antenna may include separate antenna sections in combination with a power
35 divider for intercoupling the transmission line to the

-5-

used for exciting these filaments. The filaments may be disposed either inside the balloon or within the skin of the balloon. In another embodiment of the invention, the antenna means is comprised of a
5 plurality of spacedly disposed antenna wires arranged about the balloon near the inside surface thereof, and commonly coupled to the transmission line.

In accordance with still a further feature of the present invention, there is provided a triaxial
10 fiberoptic/RF cable that is in the form of a fiber core having multiply deposited layers on the core, including a conductive layer defining a conductor, a dielectric coating defining an insulating layer and an outer conductive layer defining an outer conductor.

15 In accordance with still a further embodiment of the present invention, the balloon itself is constructed of a compliant material that is either loaded with a lossy material or coated with a flexible material sufficiently loaded with lossy particles to
20 allow for absorption of microwave energy in the balloon directly. Also, the fluid within the balloon may be of a type having lossy particles in suspension. The lossy material used may include ferrite or graphite materials.

25 IV. Brief Description of the Drawings

Numerous other objects and advantages of the invention should now become apparent upon a reading of the following detailed description, taken in conjunction with the following drawings, in which:

30 FIG. 1 is a diagram of one embodiment of the present invention, employing a microwave balloon catheter with a fiberoptic temperature sensor;

FIG. 2 is a cross-sectional view at the balloon end of the apparatus;

-7-

FIG. 18 illustrates the triaxial fiberoptic/RF cable as in accordance with the present invention adapted to transmit RF energy to a ferrite sleeve;

5 FIG. 19 is a further view of the embodiment of FIG. 18 showing further details;

FIG. 20 is a cross-sectional view of the antenna of the antenna construction of the present invention showing, in solid lines, a cross-section of one-half of the far field antenna array pattern, each of the
10 three antenna elements, and in dotted lines the near field heating pattern resulting from the superposition of the electromagnetic energy pattern generated by the three antenna elements;

FIG. 21 is a cross-sectional view of the antenna
15 of FIG. 1 along the lines 21-21;

FIG. 22 is a cross-sectional view of the antenna of FIG. 20 along the lines 22-22;

FIG. 23 is a cross-sectional view of the antenna of FIG. 20 along the lines 23-23;

20 FIG. 24 is a cross-sectional view of the antenna of FIG. 20 along the lines 24-24;

FIG. 25 is an illustration of an insulated dipole in an ambient medium used to depict the algebraic parameters needed for calculating the optimum
25 transformation of parameters;

FIG. 26 is a plot of frequency versus power ratio in decibels for the antenna of the invention;

FIG. 27 is a side view of an optional embodiment of the invention employing a lossy sleeve;

30 FIG. 28 is a cross-sectional view of an alternate embodiment of the outermost end of the antenna construction;

FIG. 29 is an enlarged fragmentary view of FIG. 28; and

-9-

melting may be the result of interaction with the water molecules' vibration energy levels, whereas microwave energy absorption in plaque may be the result of interaction with the water molecules' dipole moment or rotation energy levels.

In accordance with the present invention for successful delivery of microwave energy to the plaque, a highly flexible miniature transmission line is used, that can transmit sufficient radio frequency or microwave power to the load (plaque). This transmission line is to be kink-free, because of the requirement of relatively small turning radii.

In accordance with the present invention, the antenna system is to be designed to deliver microwave energy to a specific layer of plaque without heating wall tissue during pressure application by the balloon. The liquid that inflates the balloon preferably does not absorb any substantial microwave energy. It is instead preferred that the energy be concentrated at the plaque rather than in the liquid itself that causes the balloon's expansion.

In connection with certain fabrication techniques for the highly flexible miniature transmission line, reference is made to description set forth hereinafter relating to FIGS. 20-30.

In accordance with the present invention, there are now described a number of techniques for providing control of the quantity of microwave energy that is coupled to coronary vessel plaque without heating vessel tissue. A collinear antenna array is provided inside the balloon or between two balloon surfaces (balloon inside a balloon). In accordance with one embodiment of the invention, a printed microstrip circuit radiator or antenna pattern is configured in

-11-

FIG. 14 shows the antenna A extending through the balloon B and having at its tip T a concentric layer of ferrite material that may have a Curie temperature in the 400°C-500°C range. Microwave energy is rapidly absorbed in the ferrite when this material is at a current maximum of the antenna. The primary function of this hot tip (when the ferrite is at the far end of the antenna) is to melt plaque (ablation). This is used for those cases where the artery is fully blocked by plaque, and it would therefore be necessary to remove some plaque in order to insert the balloon. In FIG. 14, note the plaque volume at V. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out.

As indicated previously, FIG. 27 herein teaches the use of a lossy sleeve 80 for focused heating. An alternate embodiment is to employ two ferrite sleeves F1 and F2, as illustrated in FIG. 14, some distance apart along the antenna axis but outside of and essentially in front of the balloon. In this regard, the arrow A1 in FIG. 14 illustrates the direction of insertion of the antenna structure.

As indicated previously, FIG. 14 shows a two-ferrite geometry. The ferrites F1 and F2 heat through the plaque (occluded artery) using microwave frequency F1. To withdraw the antenna back through the plaque and avoid sticking, the ferrite F2 is tuned to a frequency F2. It remains hot to allow the antenna to be withdrawn prior to inserting the balloon and using the antenna in its normal temperature plaque welding mode. Also, this ferrite, hot tip antenna may be completely removed from the catheter in a different antenna design employed for low temperature operation.

Reference is now made to one embodiment of the present invention illustrated in FIGS. 1 and 2 herein.

-13-

energy absorption within the sleeve volume. Further embodiments of the invention cover this feature, such as will be illustrated and described in further detail herein in FIGS. 18 and 19.

5 Reference is now made to one embodiment of the present invention illustrated in FIGS. 1 and 2. This embodiment illustrates the microwave balloon catheter 1 with a fiberoptic temperature sensor. A cross-section schematic of the balloon end is illustrated in
10 FIG. 2. The balloon 12, it is noted, is secured to the distal end of the catheter member 1. The catheter member 1 has three lumens for carrying, respectively, the microwave coaxial transmission line 2, the
15 fiberoptic cable 3, and the channel 4, which is for the coupling of the electrically low loss fluid 13 to the balloon 12 for inflation purposes.

 FIG. 1 also illustrates, in the system, a microwave signal generator 7 that includes fiberoptic temperature processing circuitry. The generator 7, it
20 is noted, couples with the cable 6 and also the fiberoptic cable 5. These cables are continuations of the aforementioned cables 2 and 3.

 FIG. 1 also illustrates the fluid source 8, which may comprise a pump for pressurizing the fluid,
25 connected to the channel 4. As indicated previously, the fluid 13 pumped from the source 8 is preferably a low loss tangent liquid or gas that is adapted to minimize microwave or radio frequency energy
 absorption.

30 The balloon 12 is inflated by means of the liquid 13 injected into it under pressure at the entrance port 10. FIGS. 1 and 2 also illustrate a microwave antenna 11 that supplies electromagnetic energy to the liquid 13 for, say, a period of 30 seconds. The
35 liquid 13 is low loss so that the energy from the

-15-

length. The balloon length and length of the plaque deposit should coincide with the antenna length, as measured along the balloon axis. Alternatively, the collinear array may be positioned along the axis of the balloon and inside the balloon, as depicted previously in FIG. 1.

A reference is now made to FIGS. 3-6 for further embodiments of the antenna construction. FIG. 3 illustrates the collinear array antenna 65 coupled from the coaxial transmission line 2. The antenna 65 is provided in a spiral or helical configuration. In this embodiment of the invention, it is noted that the antenna is disposed substantially exclusively inside the balloon. However, in the alternate embodiment of FIG. 4, it is noted that the spiral or helical configuration of the collinear array antenna is embedded in the balloon skin.

Reference is now made to FIG. 5 for still a further embodiment of the present invention. This embodiment employs two separate collinear array antennae 68A and 68B embedded in opposite sections of the balloon skin. These antennae are fed from the coaxial line 2 by means of a power tee or power splitter, illustrated at 69 in FIG. 5.

Reference is now made to FIG. 6 for a further embodiment of the present invention employing three separate collinear array antennae 70A, 70B and 70C. In this embodiment, each of these antennae is provided inside the balloon skin, as illustrated. Each of these antennae may couple to its own separate coaxial microwave transmission line. For this purpose, the catheter member, such as member 1, illustrated in FIG. 1, may be provided with means for accepting each of these separate transmission lines. In all embodiments of FIGS. 2-6, a fluid 13 is contained in the balloon

-17-

of the spiral radiator. The overall antenna structure of FIG. 9 may be comprised of a cylindrical core 82. This core 82 may be of a rubberlike material, and may be hollow, so as to accept an optical fiber. The
5 surface of the core 82 may be coated with a thin film of highly conductive metal to provide a ground plane, as indicated at 83 in FIG. 9. Next, a thin dielectric coating or film is provided over the entire ground plane surface. This is illustrated at 84 in FIG. 9.
10 The dielectric coating may be, for example, titanium dioxide. A conductive antenna pattern is printed, as illustrated at 85 in FIG. 9, over the dielectric film surface. The pattern 85 may be provided in a continuous spiral patch, as illustrated in FIG. 9, or,
15 alternatively, a wraparound radiator may be provided as illustrated at 87 in FIG. 10.

In the embodiment of FIG. 9, the coaxial transmission line that feeds microwave or radio frequency energy to the printed radiator pattern may
20 be connected at one end of the radiator. The cylindrical geometry is well suited for the application of balloon angioplasty. However, a simple version for heating plaque may employ a flat antenna geometry as illustrated in FIG. 8. In FIG. 10 the
25 ground plane may be curved to match the balloon curvature lengthwise or remain straight and parallel to the balloon axis.

Reference is now made to FIG. 11 for still another embodiment of the present invention in the
30 form of a guide wire antenna system. The guide wire essentially provides some stiffness to the catheter and makes it easier to guide the catheter along the artery channel. The guide wire itself may be employed to form the center conductor of a feed coaxial
35 transmission line. In this regard, in FIG. 11, note

-19-

relatively closely coupled to the elements 97. The elements 97 in turn radiate microwave energy into the plaque.

Reference is now made to FIG. 13 for still a further embodiment of the present invention. FIG. 13 illustrates the balloon 100 as connected to a group of thin wire filaments 104 that are disposed at or near the inner balloon surface. This grouping of filaments or wires provides a substantially expanded center conductor for radiation directly into the plaque. In the embodiment of FIG. 13, the filaments 104 may be disposed in a fanned-out arrangement about substantially the full circumference of the balloon.

The conventional balloon construction employed in balloon angioplasty is normally manufactured using a clear, low microwave loss plastic material. However, in accordance with the present invention, there is now proposed a technique of heating plastic with microwave energy when the balloon surface is in intimate contact with the plaque. This technique of the present invention is characterized by a balloon loaded with a lossy ferrite or graphite material, such as a ferrite or graphite powder, that permits the balloon material to absorb microwave energy and therefore heat up. Alternatively, a similar lossy coating may be employed on the balloon surface to absorb microwave energy. The energy is provided by a microwave antenna located inside the balloon. The coated (or both coated and loaded) balloon serves two important functions. Heat may be directly applied to the surface of the plaque without the microwaves depending on the plaque material to have sufficient electrical loss (loss tangent) for heat-up, and the balloon may act as an attenuator of microwave energy to control the amount of microwave energy radiated directly into the plaque.

-21-

have an optical capability. This optical capability could be used for several purposes, i.e., visual observations, temperature sensing, lasing, etc.

5 The basic triaxial applicator is illustrated in FIG. 18 and is comprised of a fiberoptic cable 110, which is the heart of the system. For the particular application to microwave balloon angioplasty, the fiberoptic cable is used for temperature sensing purposes. A conductive coating, illustrated in FIG. 10 18 by the coating 112, is applied to the fiberoptic cable. This coating becomes the microwave carrying portion of the microwave/fiberoptic system.

A fiberoptic coating 114 is then applied to the conductive coating. The dielectric layer 114 is of 15 proper dielectric value and thickness to make the cable a preferred 50 ohm transmission line. Another conductive coating 116 is applied to the dielectric layer to form the outer conductive shield of the cable. Reference is also now made to the cross- 20 sectional view of FIG. 19 that furthermore shows the system as employed with a ferrite sleeve 120. The antenna system, including in particular the inner conductor 112 at its tip 113, may accommodate the ferrite sleeve 120. This device converts microwave 25 energy to thermal heat in the ferrite sleeve. The fiber core may be used for the purpose of temperature sensing in association with a feedback system for control of the temperature of the ferrite sleeve. It may also find other applications in medicine, such as 30 for cauterizing. The embodiment disclosed in FIG. 19, in particular, is used to melt or heat plaque in arteries.

Reference is now made to FIGS. 20-24 for an illustration of a microwave collinear array antenna in 35 the form of an applicator 10 for uniform heating of a

-23-

shown in FIG. 21 from the above-cited reference, the effect of such resistance is to significantly change the radiation pattern of the antenna and therefore, in the present application, its heating pattern for hyperthermia. The collinear array applicator 10 of the present invention is therefore provided with the appropriate value of resistance about one-quarter wavelength from the end of the distal section. By changing the applied frequency, or the location of the resistor, the distribution of heat around the applicator may therefore be changed or "steered" in many directions.

At the proximal end of the antenna array 10, a coaxial impedance matching transformer is provided, in the form of a dielectric cylinder 26 concentric with and external to the outer conductor 16. The dielectric cylinder 26 is covered with a metallic cylinder 27, which is electrically shorted to outer conductor 16 at proximal end A. A dielectric outer envelope 14 extends over the full length of cylinder 27 and distal section B-E. The transformer minimizes the reflected power within the feed transmission line and also prevents leakage of antenna currents along the outside of the array applicator 10. By judicious selection of operating parameters, both functions (minimizing reflected power and leakage prevention) occur at approximately the same operating frequency. The operating parameters of the coaxial impedance matching transformer are based on the theoretical equations developed by R.W.P. King, ("The Electromagnetic Field of an Insulated Antenna in a Conducting or Dielectric Medium," R.W.P. King et al., IEEE Transactions on Microwave Theory and Techniques, Vol. MIT-31, No. 7, July 1983).

-25-

elements at the distal end of the array (and decreasing the spacing between elements), a higher sectional antenna gain is achieved, as compared to the more proximal section B-C, which will have a lower gain because it is a single $(3\lambda/2)$ element.

More specifically, the square of the electric field for the half-wavelength ⁽¹⁾, full wavelength linear ⁽²⁾ and $3/2$ wavelength ⁽³⁾ antennae in free space, shown below, provides an indication of the radiated power distribution for the collinear array in lossy material (J.D. Jackson, "Classical Electrodynamics," J. Wiley, 1975, 2nd ed., pp. 402-403):

$$\begin{aligned}
 (1) \quad & \text{For } \frac{\lambda}{2} \text{ Antenna: } E^2 \propto \frac{\cos^2 \left(\frac{\pi}{2} \cos \theta \right)}{\sin^2 \theta} \\
 (2) \quad & \text{For } \lambda \text{ Antenna: } E^2 \propto \frac{4 \cos^4 \left(\frac{\pi}{2} \cos \theta \right)}{\sin^2 \theta} \\
 (3) \quad & \text{For } \frac{3\lambda}{2} \text{ Antenna: } E^2 \propto \frac{\cos^2 \left(\frac{3\pi}{2} \cos \theta \right)}{\sin^2 \theta}
 \end{aligned}$$

wherein θ is measured from the longitudinal axis of the antenna.

The full wave antenna, distribution (C-E), can be considered as resulting from the coherent superposition of the fields of two collinearly adjacent half-wave antennae patterns B_2 and B_3 excited in phase; the power intensity at $\theta = \pi/2$ is 4 times that of half-wave length antenna. Thus, the extreme distal section (C-E) of two series connected half wave antennae radiates 6 dB more power per solid angle than the three half wave length section (B-C). Based on geometric reasoning, the total power radiated by the

-27-

the proper transformer operation using the criterion that the complex propagation constant k_L of the transformer dielectric is the same as the k_L of the distal section. A uniform silver ink coating is then applied over the polyacrylamide material to form a second conductive layer 27. This second conductive layer 27 is present only over the length of the proximal section. It is applied in a manner which creates a short circuit to the silver ink outer conductor 16 at proximal end A but leaves an open circuit between it and the outer conductor 16 at point B. The outer PTF coating 14 is then applied over the proximal section A-B or continued from the distal section.

This coating 14 permits the probe to operate within wide limits of variations of temperature, tissue dielectric constant and electrical conductivity. A 10 mil thick coating of PTF permits the array to maintain a constant heating pattern (ignoring the effects of heat loss or gain by conduction or convection) for a change in the dielectric constant of tissue from 30 to 80 which may occur during heat application.

Within the dielectric coating 14, fiberoptic thermometry sensors 24 may be embedded. A sensor, such as that produced by the Luxtron Corporation ("16-Channel Fiberoptic Thermometry System with Multisensor Arrays for Thermal Mapping," Wickersheim et al.) may be appropriately modified for application to the array 10. Several linear phosphor sensors 24 about 0.25 mm in diameter (10 mils) may be embedded in the outer dielectric 14. The phosphor sensors 24 utilize the temperature dependence of the fluorescent decay time of the phosphor to determine temperature.

-29-

The general theory of the insulated antenna applies when the wave number of the ambient medium is large compared to that of the insulating sheath and the cross-section of the antenna is electrically small. That is

$$|k_4/k_2|^2 \ll 1; |k_4/k_3|^2 \ll 1; (k_2b)^2 \ll 1; (k_3c)^2 \ll 1. \quad (1)$$

Subject to these conditions and with the time dependence $e^{i\omega t}$, the current in the central conductor is

$$I(z) = I(0) \frac{\sin k_L(h-|z|)}{\sin k_L h}$$

$$I(0) = V_0 Y_0 = V_0 / Z_0 \quad (2a)$$

where admittance is:

$$Y_0 = -(i/2Z_0) \tan k_L h. \quad (2b)$$

For a dielectric with two layers:

$$k_L = k_2 \frac{\ln(c/a) + \frac{1}{2} \frac{\ln(b/a) + n_{23} \ln(c/b)}{\ln(c/a) + n_{24} F}}{\ln(c/a) + F} \quad (3)$$

$$Z_0 = (\omega \mu_0 k_L / 2\pi k_2) \frac{1}{[\ln(b/a) + n_{23} \ln(c/b) + n_{24} F]} \quad (4)$$

$$\text{where } n_{23} = k_2^2 / k_3^2, \quad n_{24} = k_2^2 / k_4^2,$$

$$\text{and } F = H_0^{(1)}(k_4 c) / H_1^{(1)}(k_4 c);$$

wherein $H_0^{(1)}(k_4 c)$ and $H_1^{(1)}(k_4 c)$ are zero and first order Hankel functions of the first kind.

These formulas can be simplified by the introduction of an effective wave number K_{2e} and an

-31-

transformer must match with β_L , and $\beta_L d = \pi/2$ gives the required length of the transformer. β_L is the real part of k_L of Equation 6. The transformer length is the length of the proximal section. Proper impedance
5 matching of the collinear antenna array is therefore dependent on the value of k_L . For the proper choice of dielectric inside the transformer and length of transformer, a high value of impedance will exist at the input (Section B). This will effectively isolate
10 the array from the feed line, and with the proper location of the input of the transformer from gap 5, give a collinear array which is properly matched to the 50 ohm feed line.

FIG. 26 shows the ratio of reflected power (P_R)
15 to transmitted power (P_T) in decibels in the coaxial line for a 10 cm long, 3 gap, collinear array of 2 millimeter diameter made in accordance with the invention. The frequency f_0 is the frequency which yields the highest value of terminating impedance for
20 the array wherein the elements of the array are harmonically related. For the 10 cm device in the example, the collinear array that achieves the uniform heating pattern consists of the elements depicted in the distal section B-E of FIG. 20, wherein the
25 frequency is 915 megahertz. The transformer length is about 1 centimeter with a PTF dielectric inside the transformer, having a dielectric constant of 40.

As shown in the optional embodiment of FIG. 27, a
lossy sleeve 80 comprised of ferrite cores or beads
30 formed in the shape of a cylinder with an inner bore may be disposed about the applicator 10 at the distal end thereof. Preferably, the inner diameter of the bore in sleeve 80 forms a press fit with the outer diameter of the applicator 10 and is held in place
35 along the longitudinal length of the applicator by a

-33-

conductor 16 of the antenna array is terminated by a radially inwardly extending ring, shown as sections 16a and 16b. A beam steering resistor 22 may be disposed along the longitudinal axis of the antenna in the path of inner conductor 20, as shown. Alternatively, an equivalent beam steering resistor 21 may be formed as a circular ring embedded in outer insulator 14.

The inner walls of ring sections 16a and 16b are insulated from resistor 22 or (in the event resistor 22 is not present) from inner conductor 20 by dielectric disk 62. The inner conductor is extended radially from the longitudinal axis by disk-like conductor member 18c which is integral with coaxial conductor 18a encased in dielectric 14.

The collinear applicator array 10 may be connected to a commercially available coaxial cable, as shown in FIG. 30, by means of a flexible coaxial connector adaptor 60. This type of connector will eliminate the need to use expensive commercially available SMA connectors. In addition, the size of SMA connectors may be excessive in diameter for certain applications, thereby creating the need for a special connector whose diameter will conform to the diameter of the collinear applicator.

As shown in FIG. 30, the adaptor comprises a laminated metal conductive ring 40 or ferrule having an inner diameter conforming to the outer diameter of the outer conductor 16 of applicator 10 affixed around the outer conductor. The adaptor of FIG. 30 may be located at various positions along the transmission line. The outer conductor 16, dielectric core 18 and inner conductor 20 of applicator 10 are allowed to extend longitudinally outward from the proximal end of the applicator, with the core 18 extending beyond the

-35-

1. Angiographic techniques for access to arterial or venous components (using fluoroscopy);

2. Endoscopic techniques for access to the urethra, prostate, bladder, ureters, and renal pelvis
5 via retrograde cannulation (using fiber optic endoscopy, i.e., cyrtoscopes);

3. Percutaneous techniques for direct access by way of so-called antegrade nonsurgical approach through the flank or back to the renal pelvis; ureter
10 and bladder (using CT, ultrasound, fluoroscopic or even endo-urolologic equipment).

The currently available state-of-the-art imaging equipment (particularly ultrasound and CT) allows visualization and direct puncture of masses in the
15 neck, abdomen, pelvis, and extremities. Under ultrasonic or CT guidance, long, small diameter needles (18-23 gauge) are easily introduced through the skin and into superficial or deep lesions. In a similar manner, the applicator probe 10 could be
20 easily introduced into these lesions through any number of widely available biopsy needles.

The same techniques and equipment can be used for the relatively non-invasive (i.e., non-surgical) access and treatment of other anatomical sites. For
25 example, the gastrointestinal tract, specifically, the biliary system, is routinely approached by endoscopic means (ERCP-endoscopic retrograde cannulation of the pancreas), as well as percutaneously by direct
intercostal puncture and catheterization of the liver
30 and bile ducts for diagnosis and treatment of malignant and benign obstructions (due to hepatic, biliary, pancreatic, and lymph node diseases). Other lesions of the GI tract, such as in the stomach, are

-37-

from the generator thereof to the balloon structure. The transformer section of the collinear array antenna, such as illustrated in FIGS. 11 and 20, is employed to ensure good impedance matching and no
5 antenna current leakage along the outer surface of the outer conductor of the coax line. Various forms of transmission line structure may be employed inside the balloon or on the inside surface of the balloon, or even between two balloons, one inside the other.

10 The radiating transmission line structure within the balloon may be a simple two wire arrangement, or may employ multiple wire combinations connected together so that the electric field of the wires extends into the plaque, thus avoiding the heating of
15 artery tissue. In another arrangement, a leaky coax wire may be of various cross-sectional geometries. They may be, for example, microstrip or strip line, as illustrated hereinbefore.

By varying the spacing between these conductors,
20 the number of conductors employed, and the electrical phasing of each conductor, a specific electric field distribution can be achieved in the plaque region. In this regard, refer to the previously described FIG. 6 that shows antenna elements. Also refer to FIG. 13.
25 Thus, in addition to the use of wires, one can use several collinear array antennae, as illustrated in FIG. 6. For example, if four collinear array elements are used, forming a square pattern, and the elements are spaced one-half wavelength apart, current phasings
30 of 0° , 90° , 270° , and 360° or 0° will place the resultant heating pattern in the center of the square.

For the transmission line system illustrated in FIG. 31 herein, the resultant heating pattern is larger, or, in other words, the electric field extends
35 outside the square to a greater extent in comparison

-39-

flexible inside the balloon. Although the helix can radiate in several modes, the most commonly used modes for antenna practice are the axial and normal modes. The axial mode provides maximum radiation along the helix axis. It occurs when the helix circumference is on the order of one wavelength. The normal mode, which yields radiation broadside to the helix axis, occurs when the helix diameter is small with respect to the wavelength. Higher order radiation modes are also possible. For example, when the helix dimensions exceed those required for the axial mode, higher order radiation modes exist. The resultant pattern is referred to as a conical or multi-lobed pattern. It is this mode of radiation that is insensitive to structures or materials located inside the helix.

The basic radiation patterns for free space helices are shown in FIG. 31. The basic helix geometry is also indicated. The pertinent design parameters for a free space environment are:

D = diameter of helix (center to center)
C = circumference
S = spacing between turns
a = pitch angle
N = number of turns
L = axial length of helix
d = diameter of helix
l = length of one turn

The helix antennae can be designed with bifilar, quadrifilar or multifilar windings. They can be designed with non-uniform diameters and tapered diameters. Various types of tapered designs are shown in FIG. 34. The envelope taper with either constant pitch angle or constant spacing between turns represents a design shape suitable for balloon application. Various possible constructional and feed

-41-

dielectric sheath. The thin film process technology application is illustrated herein in FIG. 36. FIG. 36 shows the center conductor wire 200. The wire 200 is then coated with a dielectric material, as indicated at 202. On the dielectric material there is then evaporated or sputtered a thin metallic film forming the outer conductor as indicated at 204 in FIG. 36. The deposition of the outer layer may be by physical vapor deposition or by chemical vapor deposition (CVD).

The next step is to preferably wrap a metal helix on the coax cable for improved insertion loss and mechanical integrity. Dielectric materials may be deposited on the cable to create the aforementioned transformers.

Having now disclosed a number of embodiments of the present invention, it should be apparent to those skilled in the art that numerous other embodiments and modifications thereof are contemplated as falling within the scope of the present invention as defined by the appended claims.

-43-

5. A microwave catheter system for heating arterial plaque as set forth in claim 4 including a pair of sensors for measuring temperature at two locations within the balloon.

5 6. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said antenna means comprises a collinear array antenna.

 7. A microwave catheter system for heating arterial plaque as set forth in claim 6 wherein the
10 collinear array antenna is disposed inside the balloon.

 8. A microwave catheter system for heating arterial plaque as set forth in claim 6 wherein the collinear array antenna is disposed within the skin
15 forming the balloon.

 9. A microwave catheter system for heating arterial plaque as set forth in claim 6 wherein the collinear array antenna is formed in a spiral to provide full balloon circumferential coverage.

20 10. A microwave catheter system for heating arterial plaque as set forth in claim 6 wherein the collinear array antenna is formed in a helix to provide full balloon circumferential coverage.

-45-

17. A microwave catheter system for heating arterial plaque as set forth in claim 15 wherein said radiator is of annular configuration, having an outer radiating strip.

5 18. A microwave catheter system for heating arterial plaque as set forth in claim 15 wherein said radiator includes a hollow member coated with a thin conductive film to form a ground plane, a thin
10 dielectric film over the ground plane, and a conductive antenna pattern printed over the dielectric film surface.

19. A microwave catheter system for heating arterial plaque as set forth in claim 18 wherein said antenna pattern is in a spiral form.

15 20. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said transmission line means has a center conductor of sufficient stiffness to form a guide wire.

20 21. A microwave catheter system for heating arterial plaque as set forth in claim 20 including impedance matching means along said center conductor at the location where the center conductor enters and leaves the balloon.

25 22. A microwave catheter system for heating arterial plaque as set forth in claim 21 wherein the transmission line means has an outer conductor except at positions within the balloon, a tip of the center conductor extending beyond said balloon.

-47-

29. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said balloon is constructed of a complaint material loaded with a lossy material to allow the balloon skin to
5 absorb microwave energy directly.

30. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said balloon is coated with a lossy material to absorb microwave energy.

10 31. A microwave catheter system for heating arterial plaque as set forth in claim 29 wherein the lossy material includes ferrite or graphite material.

32. A microwave catheter system for heating arterial plaque as set forth in claim 1, wherein said
15 antenna means comprises a helical antenna.

33. A microwave catheter system for heating arterial plaque as set forth in claim 32, wherein said helical antenna is tapered.

34. A microwave catheter system for heating
20 arterial plaque as set forth in claim 1, wherein said antenna means comprises a segment of transmission line within said balloon.

35. A microwave catheter system for heating arterial plaque as set forth in claim 34, wherein said
25 transmission line section within the balloon is comprised of a center conductor, a dielectric material disposed about the center conductor and a thin metallic film deposited over the dielectric material and forming an outer conductor.

-49-

40. A collinear array antenna as set forth in claim 38 including a ferrite member arranged over said antenna for providing enhanced heating.

5 41. A system for heating arterial plaque having a proximal section adapted to be coupled to a source of electromagnetic energy and a distal section for radiating said energy, comprising: a collinear array antenna formed by a continuous inner conductor, and a distal end in the distal section surrounded by
10 dielectric material and an interrupted coaxial outer conductor longitudinally extending at one end from the proximal section to another end at the distal section and wherein the interruptions are in the form of circumferential gaps periodically spaced along the
15 coaxial conductor at interrelated harmonic wavelengths to radiate a substantially uniform beam pattern of electromagnetic energy about the periphery of the antenna and an impedance matching means at the proximal section.

20 42. A system for heating arterial plaque as set forth in claim 41 in combination with a catheter member supporting at the distal end thereof a inflatable balloon and furthermore comprising a pair of impedance matching means at either side of said
25 balloon.

2/10

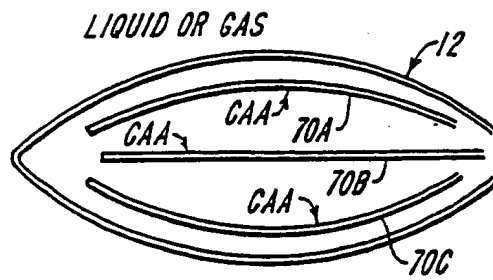


FIG. 6

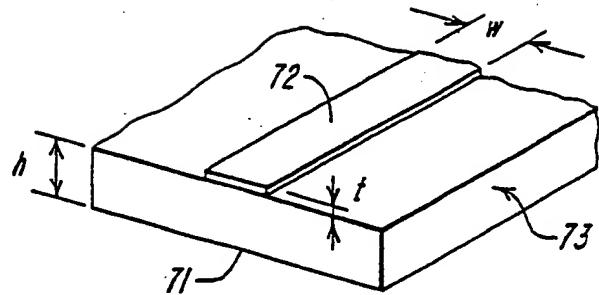


FIG. 7

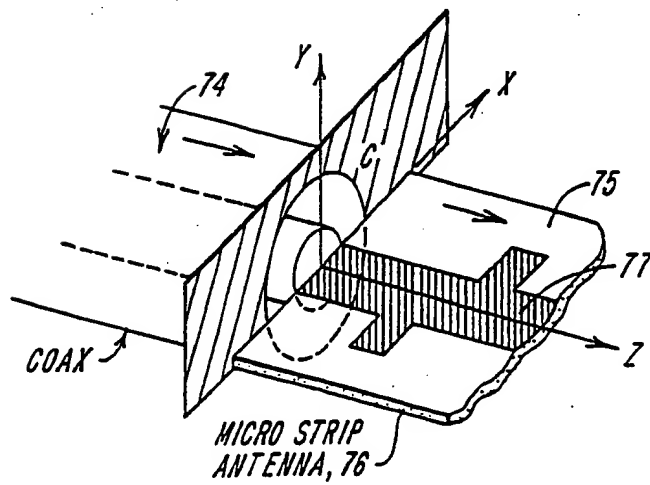


FIG. 8

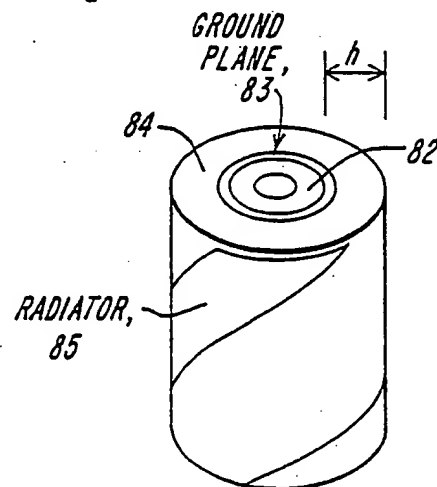


FIG. 9

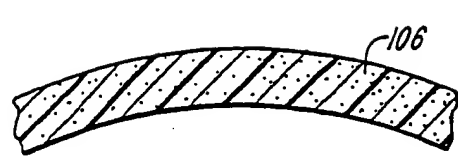


FIG. 15

4/10

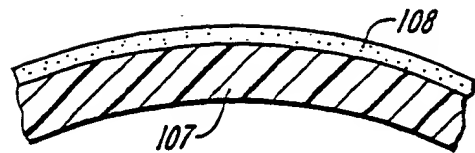


FIG. 16

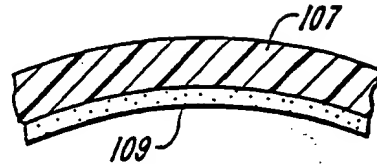


FIG. 17

FIG. 18

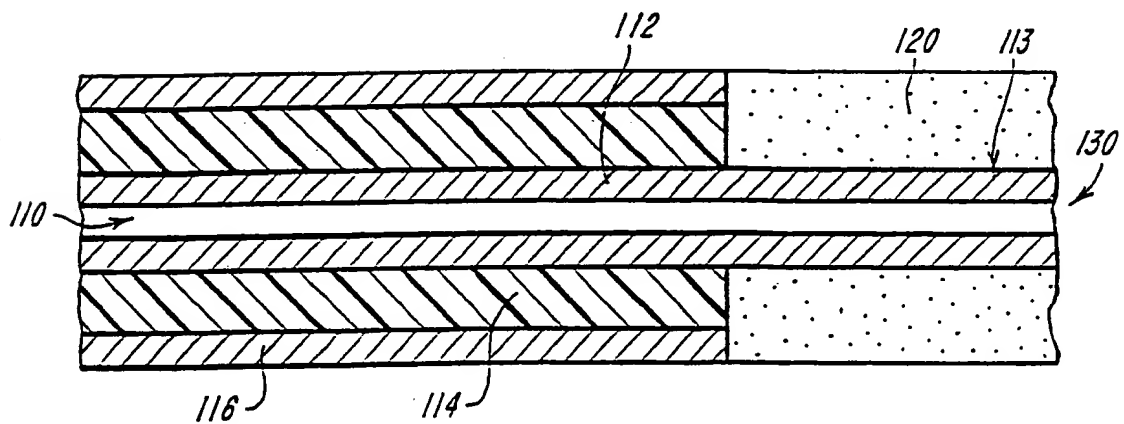
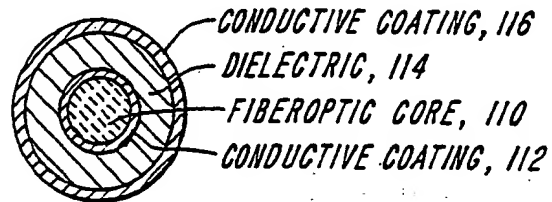


FIG. 19

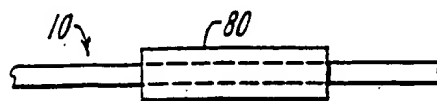
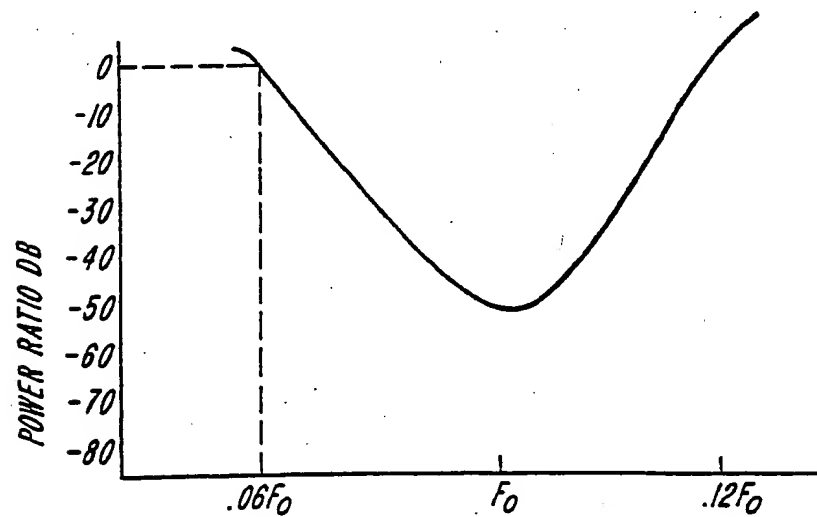
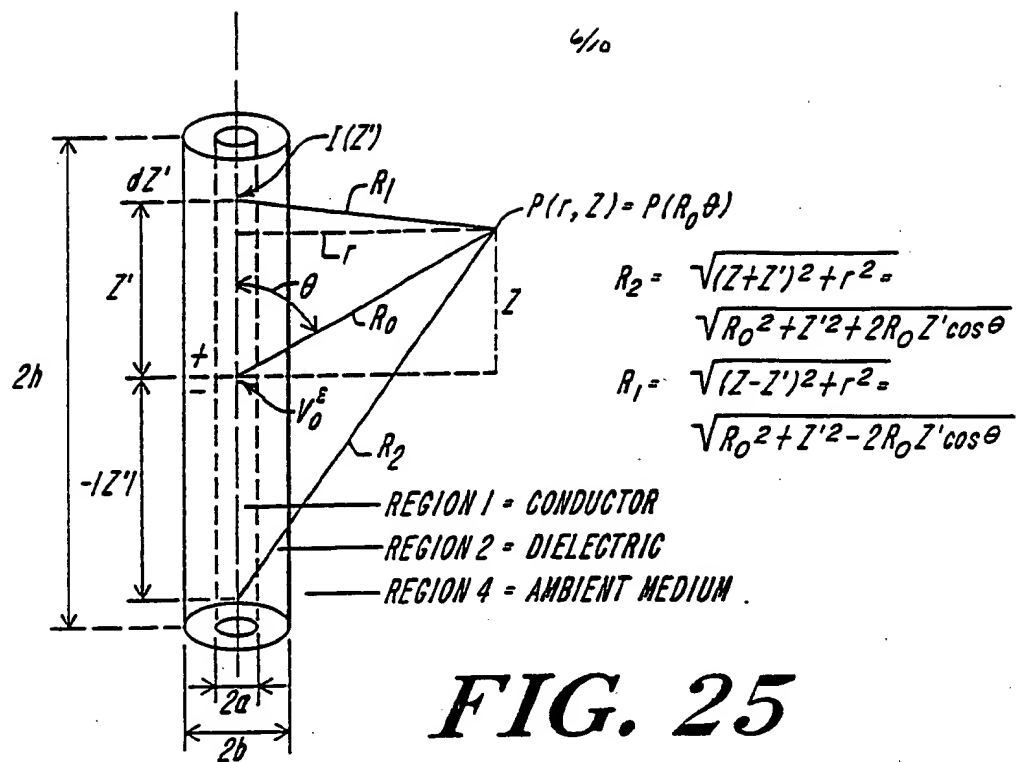


FIG. 27

2/10

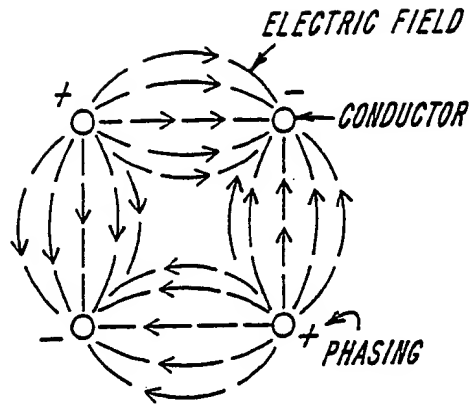


FIG. 31

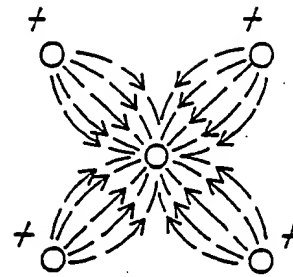


FIG. 32

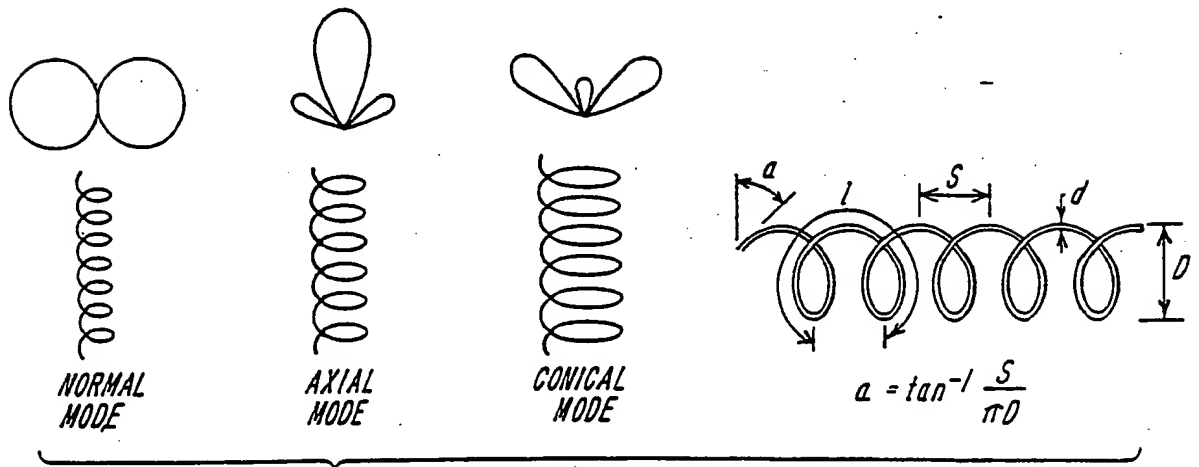
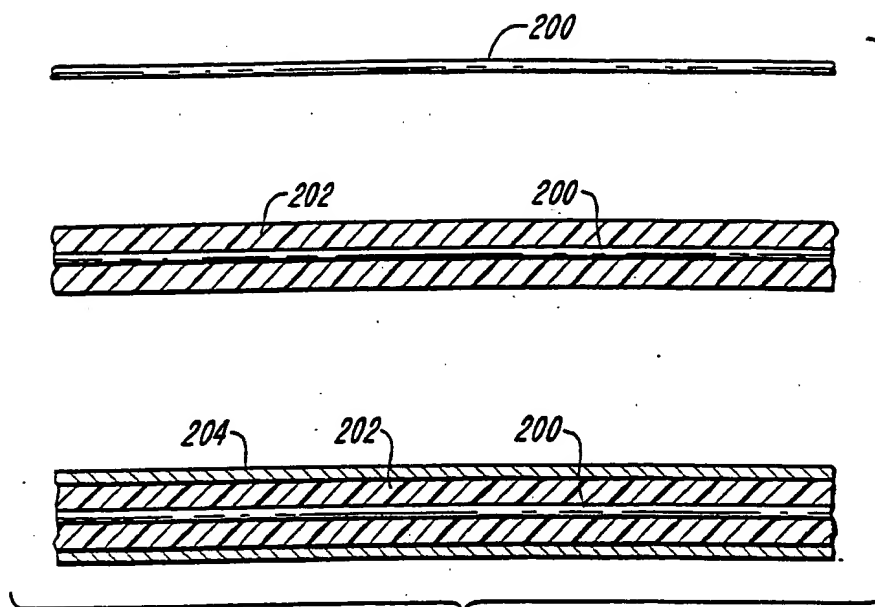


FIG. 33

10/10

**FIG. 36**

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US,A, 4,681,122 (WINTERS) 21 July 1987. see entire document.	1
X Y	GB,A, 1,188,490 (FRITZ) 15 April 1970. See entire document.	38,41 21,39, 40,42
Y	GB,A, 2,122,092 (JAMES) 11 January 1984. See entire document.	15,16, 29-31, 40
Y	EP,A, 0,105,677 (SOGAWA) 18 April 1984. See pages 1-18.	1,22, 38,41
A	DE,A, 3,516,830 (DORNBER) 13 November 1986. See entire document.	23-26
Y	EP,A, 0,251,745 (KITAGAWA) 07 January 1988. See entire document.	9,10, 32,33